

## REMARKS

Prior to entry of this Supplemental Amendment, claims 2-10 and 12-42 are pending in the application. This paper cancels no claims. Accordingly, after entry of the response, claims 2-10 and 12-42 remain pending.

### *I. Response to Notice of Non-Compliant Amendment*

The Examiner issued a Notice of Non-Compliant Amendment on February 7, 2006, alleging proper status identifiers were not included for each claim. The Applicant has added the proper status identifiers.

### *II. Claim Objections- Claims 25, 30 and 40*

The Examiner objected to claims 25, 30 and 40 for various informalities. Specifically, the Examiner requested the word "and" be inserted in claim 25 between "configuration" and "a", the word "wherein" be inserted into claim 38, and the word "integral" be removed from claim 40. The Applicant has amended these claims accordingly.

### *III. Rejections Under 35 U.S.C. § 112*

The Examiner rejected claims 2-10 and 12-42 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner alleges the specification does not disclose how the observation window 14 of the present invention is adapted to isolate the light source from the lumen, as claimed in claim 41. In response thereto, the Applicant has amended claim 41 to more particularly recite the relationship between the observation window, speculum interior, insufflation chamber, and coupling means. The Applicant respectfully submits this amended claim 41 overcomes the Examiner's rejection under § 112.

Next, the Applicant has amended claims 41 and 42 to eliminate the reference to a "connection means," instead reciting the limitation of a "coupling means." The Applicant respectfully submits this amendment overcomes the Examiner's rejection under § 112. The Applicant respectfully submits, however, that the fibre optic light head and coupling means of the present invention are not necessarily the same. For example, paragraph 0038 of the specification explicitly states the "[f]ibre optic head 5 further includes means 7 for the releasable attachment of a light source." Thus, the fibre optic light head may include a coupling means, but is not necessarily itself (or solely) the coupling means. Further, as stated in paragraph 0054 and shown in Fig. 3 of the invention, a coupling means 15 may be

"attached at or adjacent to observation end 4 of speculum 1... A light source 8 is attached to coupling means 15..." Thus, it is clear from the specification that the fibre optic light head and coupling means cannot be directly equated.

The Applicant has also amended claims 2 and 18 to change the antecedent basis of the phrase "the contamination means" to read "a contamination means."

For at least the foregoing reasons, the Applicant respectfully submits the Examiner's rejections under 35 U.S.C. § 112 are overcome. Accordingly, the Applicant respectfully requests the Examiner withdraw the rejections.

#### *IV. Rejections Under 35 U.S.C. § 102- Fiore*

The Examiner rejected claims 41, 42, 10, 12-17 and 21-24 under 35 U.S.C. § 102(b) as anticipated by United States Patent No. 3,889,661 to Fiore (hereinafter "Fiore"). The Examiner alleged Fiore teaches all elements of each of these claims. For at least the following reasons, the Applicant disagrees.

Fiore teaches a transparent flange wall 19 defining an inwardly-projecting annular window, which, in combination with a cylindrical section 18, isolates a recess 27 (in which a light head 25 sits) from the interior of the barrel 11 (see Fig. 1 and col. 4, lines 7-23). The flange wall permits "a lighting means in handle or lighting unit 12, and behind wall 19, [to] transmit light down barrel 11 to the distal end" (col. 4, lines 17-19). The Examiner alleges this transparent wall 19 anticipates the observation window of the present invention. As the Examiner stated in his Office action at paragraph 7, "As to the newly added limitation to the 'observation window adapted to isolate the light source from the lumen,' note window (18,19)..." This rejection ignores certain fundamental differences between the claimed observation window and Fiore's structure.

First, although Fiore's transparent wall (18, 19) permits light to enter Fiore's barrel 11, it is not an observation window as required by independent claim 41. An operator cannot look through Fiore's transparent wall, due to its location within the barrel 11; view through the window is blocked by the annular part 26, which surrounds the transparent wall and is itself opaque. Instead, an operator looks through a lens 33 formed in an end cap unit. In particular, "end cap unit 32 is usually provided with an optical lens 33 to facilitate examination" (col. 6, lines 54-55; see generally col. 4, lines 45-58).

Additionally, the Applicant has amended independent claim 41 to more clearly require that the fluid-tight observation window extend “across the observation end of the speculum” and define, “in combination with the interior of the speculum... a fluid-tight insufflation chamber to isolate the light head from the lumen.” Fiore’s transparent wall (18, 19) cannot anticipate this limitation, because it does not extend across the observation end of the speculum. Likewise, Fiore’s lens 33 cannot anticipate this limitation, because the lens does not “isolate the light head from the lumen,” as required by independent claim 41. In any event, the chamber partially defined by Fiore’s lens 33 is not an “insufflation chamber,” as required by independent claim 41.

Next, the Applicant notes the Examiner alleges that the “tube conveying the insufflation medium does not contact the annular part (26)” in Fiore (Office action, paragraph 7). The Applicant respectfully submits Fiore teaches merely that the insufflation medium is isolated from the light *source* (i.e., lamps 25 as alleged by the Examiner), but not the lighting *head* 24.

Fiore discloses that “both suction and pressure is applied [to insufflate the colon] through a nipple or conduit 34 which projects from lighting head 21 and communicates to the interior of barrel 11 through an appropriate opening or slot 35 (not shown) in cylindrical section 18”) col. 6, line 67 to col. 7, line 3). Thus, the insufflation medium must necessarily pass through the conduit 34, which is defined in the lighting head 24 (Fig. 1; *Id.*).

By contrast, amended claim 41 requires that “the insufflation medium [is] conveyed directly from the insufflation means to the insufflation chamber by a gas conveying insufflation tube without contacting the light head.” Accordingly, since Fiore teaches that the insufflation medium *must* pass through the lighting head, it cannot anticipate independent claim 42, which requires the insufflation medium to *not* contact the light head.

For at least the foregoing reasons, the Applicant respectfully submits Fiore cannot, and does not, anticipate or render obvious amended independent claim 41. The Applicant therefore respectfully requests the Examiner withdraw his rejection and allow claim 41 over the cited reference.

The remaining rejected claims depend, either directly or indirectly, from independent claim 41. Insofar as independent claim 41 has been shown to be patentable, these

dependent claims are also patentable. The Applicant makes this statement without reference to or waiving the independent bases of patentability within each such dependent claim. The Applicant therefore respectfully requests the Examiner withdraw his rejections and allow the dependent claims over the cited reference.

*V. Rejections Under 35 U.S.C. § 103*

The Examiner rejected claims 2, 3, 5-8, 15-24, 28, 30, 31 and 33-40 under 35 U.S.C. § 103(a) as rendered obvious by the combination of Fiore and Japanese Publication No. 06-319691 to Sugiyama. The Examiner likewise rejected claims 4, 9, 29 and 32 under 35 U.S.C. § 103(a) as rendered obvious by the combination of Fiore and United States Patent No. 5,061,239 to Shiels. Additionally, the examiner rejected claim 25 under 35 U.S.C. § 103(a) as rendered obvious by the combination of Fiore and United States Patent No. 5,176,127.

The Applicant notes each of these dependent claims depend, either directly or indirectly, from independent claim 41. Insofar as independent claim 41 has been shown to be patentable, these dependent claims are also patentable. The Applicant makes this statement without reference to or waiving the independent bases of patentability within each such dependent claim. The Applicant therefore respectfully requests the Examiner withdraw his rejections and allow the dependent claims over the cited references, alone or in combination.

*VI. Allowable Subject Matter*

The Applicant thanks the Examiner for his indication that claims 26 and 27 would be allowable if rewritten in independent form, including all limitations of the base claim and any intervening claims. However, since the Applicant has demonstrated herein the allowability of all pending claims, the Applicant has at this time declined to rewrite claims 26 and 27 in such a manner. The Applicant reserves the right to rewrite these claims in independent format at a later date, if necessary.

*VII. Conclusion*


This Amendment is submitted after a Request for Continued Examination and before substantive examination of the Amendment and Response submitted on December 16, 2005. The Applicant thus respectfully requests the Examiner consider the claims as set forth in this paper, insofar as this paper supersedes the December 16 amendment.

Additionally, this Response to Notice of Non-Compliant Amendment and Supplemental Amendment is submitted within two months of the mailing of the Notice of Non-Compliant Amendment. Accordingly, the Applicant respectfully requests a one-month extension of time and authorizes a charge to Deposit Account No. 04-1415 in the amount of the corresponding fee. The Applicant believes no further fees or petitions are required. However, if any such petitions or fees are necessary, please consider this a request therefor and authorization to charge Deposit Account No. 04-1415 accordingly.

If the Examiner should require any additional information or amendment, please contact the undersigned attorney.

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Respectfully submitted,



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